REMARKS

In accordance with the above amendments, claims 46, 48 and 49 have been amended, claims 19-23, 34, 36-39, and 42-45 have been canceled and new claims 52-68 have been added. Thus, claims 46-68 remain under consideration in this application. No claim has yet been allowed.

It is believed that all of the claims presently presented, including all new claims, have clear support throughout the specification and drawings and also present a clarified image of the inventive subject matter.

Claim Rejections - 35 USC § 103

All of the claims of record remain rejected under 35 USC § 103(a) as being unpatentable over Marcenyac et al (U.S. Pat. Pub. No. 2004/014647 A1) and Granger et al (USPN 5,149,538) in view of Church (USPN 6,660,901). This rejection is again respectfully traversed.

As has been previously explained, the present invention involves deactivation of abusable substances contained in transdermal patches which is accomplished after use and during normal disposal of such a patch. The techniques and implementations of the present invention do not depend upon any attempted acts of misuse to trigger the deactivation process. Thus, the abusable substance in a transdermal patch is deactivated simply either by placement in a disposal pouch or, owing to a special patch construction, upon removal of the patch

from the skin of a user. In no event do any of the embodiments of the deactivation system of the present invention depend upon attempts at misuse.

With respect to the combination of references cited by the Examiner, Marcenyac et al, as has previously been explained, discloses a transdermal dosage device with anti-misuse aspects in some embodiments and an article including a pouch for insertion of a transdermal patch in others. Each article uses a heat or pressure-sensitive adhesive to seal the patch in a pouch or medicament layer with an associated detection material (dye) in an inactivation reservoir. No deactivation takes place with normal disposal. The devices are designed not to release a detecting dye or antagonist until the used sealed patch is tampered with.

Thus, as previously indicated, Marcenyac et al fails to disclose or suggest a disposal device or technique that deactivates the medicament on contact during normal disposal. The reference simply discloses an alternate and different approach that teaches away from applicants' approach.

An element of Claims 46-48 and 60-67 is that the container is "configured such that insertion of said skin-worn patch device properly oriented into said container causes said abusable substance in said skin-worn patch device to contact said deactivating material." This element is simply not present in Marcenyac. Furthermore, this element is not suggested in

Marcenyac because Marcenyac requires some further step beyond insertion, such as tampering. If Marcenyac were modified so that contact occurred upon insertion, one would not be able to detect subsequent tampering which is the purpose of Marcenyac's disclosure. Accordingly, Marcenyac does not suggest the claimed limitation in which contact occurs upon insertion.

Further, it is important to emphasize as previously pointed out that the Marcenyac device could not use activated carbon as a "inactivating agent". For example, the Marcenyac device contemplates co-formulation of a dye with the inactivating agent so as to produce an identifying stain on an individual attempting to tamper with the device. Activated carbon, as a non-specific adsorption agent, would bind with the dye and thus not allow the identifying dye transfer to the individual.

Moreover, with respect to certain claims such as Claim 48, neither the Marcanyac device nor any other of the cited references contemplate or suggest a deactivating system that includes incorporation of an agent selected from the group consisting of antagonists, irritants and mixtures thereof onto a portion of activated carbon. This is a very important advantage and distinction to the present invention. Because the additional agents are incorporated into carbon, they will not be released and cause harm to persons properly handling the disposal system (e.g. they are adsorbed onto carbon and therefore in an inactive state). However, if an individual attempts to extract drug from

the carbon using solvents for abuse purposes, the antagonists, irritants or mixtures thereof will be released from the carbon portion by the solvent in an activated anti-abuse state.

Likewise, Granger et al fails to teach or suggest a patch construction that incorporates a barrier that is removed upon removal of the patch from the skin of a user, as claimed. Contrary to the Examiner's view, this result does not depend on any intended use limitation, but goes to the construction of a device which has but one intended use.

For example, Claim 49 includes the element of "wherein said aspect and said patch are configured such that upon removal of said patch from skin to which said patch is adhered said aspect remains adhered to skin with sufficient adhesion to cause said separator membrane to be withdrawn from between said deactivating layer—and said source layer upon removal of said patch so that the deactivating layer contacts the source layer." It is not seen where this particular structural limitation is taught or suggested in Granger, much less Marcenyac or Church.

Whether Granger discloses a barrier that may dissolve under certain circumstances is totally irrelevant as a dissolving barrier has nothing to do with any embodiment of the present invention. Furthermore, Granger et al is clearly also irrelevant with regard to any embodiment which uses a separate disposal container, as in claims 46 to 48 and 60 to 68.

Finally, Church, the third reference in the combination, discloses the topical application of activated charcoal to the skin to absorb toxins of various types using a passive skin patch in the treatment of skin injuries such as bites, insect stings, etc. The purpose of that device is to remove materials from various types of skin wounds. The preferred embodiment combines activated charcoal with psyllium husk and operates in the manner of an absorbent bandage. That device is not intended to bind or deactivate compounds such as opioids and clearly, once the patch of Church is removed, there would be no incentive to misuse a discarded patch. Church certainly does not disclose or teach that activated carbon will, in fact, deactivate opioids or other medicaments from a patch used to administer such medicaments to a user rather than to absorb toxins from a user. The use of activated carbon in the present invention is believed beyond what would occur to one skilled in the art from any information disclosed in Church, the compounds to be deactivated and the techniques involved are quite different.

As such, there is no valid reason provided by the Examiner to support the assertion that one of skill in the art would modify the device of Marcenyac or Granger to include activated charcoal.

Moreover, Church does not specify nor contemplate incorporation of an agent selected from the group consisting of antagonists, irritants and mixtures thereof onto a portion of

activated carbon. This would be counter-productive, in that these are potentially harmful agents and not unlike the kind of materials that the Church patch intends to remove from a patient's body and, thus, could destroy the usefulness of the Church device.

To say that the product as claimed as a whole is taught by the combination of cited prior art references ignores important differences and incompatibilities between or among any combination of elements taught or suggested in the cited art and the applicants present claims. The Examiner's reference to the claim preamble further is not understood.

It is well known that "the Examiner bears the burden of presenting a prima facie case of obviousness". In re Rijckaert, 9 F.3d 1531, 28 U.S.P.Q. 2d 1995 (Fed. Cir. 1993). "A prima facie case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a prson of ordinary skill in the art." Id. The Examiner must demonstrate "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed invention does". *See* KSR International Co. v. Teleflex, Inc., 127 S.Ct. 1727, 1731 (US 2007).

Such reasons are not believed to exist but, even if reasons did exist to combine the elements of the cited references, it is

submitted that one would not achieve the claimed invention absent a clear inventive step.

For all the reasons presented above and reasons previously submitted, applicants believe that the required burden has not been met by the Examiner and that the claims have been distinguished and are presently in allowable condition. Therefore, it is respectfully requested that the Examiner reconsider his position, withdraw the rejection and allow the present claims.

Should minor issues remain which, in the opinion of the Examiner, could be resolved by telephone interview, he is invited to contact the undersigned attorney in an effort to resolve such issues and expedite prosecution of this application.

Respectfully submitted,

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